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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,629	01/29/2004	Karla Weaver	706198-2001	6763

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Bingham McCutchen LLP
2020 K Street, NW
Washington, DC 20006

EXAMINER

SCHMIDT, EMILY LOUISE

ART UNIT	PAPER NUMBER
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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/768,629	Applicant(s) WEAVER ET AL.	
	Examiner Emily Schmidt	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 2 is objected to because of the following informalities: A claim being canceled must be indicated as “canceled;” the text of the claim must not be presented (MPEP 714).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The seating portion which covers a minority of the surface area of the lumen occluding portion in which the slit is disclosed as recited in the claims contains matter new to the application. Nowhere does the specification relate that the seating portion covers a minority of the surface area of the lumen occluding portion.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 3767

regards as the invention. The term minority has not been sufficiently defined. For purposes of examination, the term minority is taken to mean less than fifty percent.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorehead et al. (US 5,984,902).

With regard to claim 1, Moorehead teaches a pressure activated valve (Fig. 3) for medical applications comprising: a housing having a lumen extending therethrough from a proximal end to a distal end thereof (Figs. 3 and 7 housing 112); and a flow control membrane extending across the lumen to control flow therethrough wherein the flow control membrane comprises a first membrane (Figs. 3 and 7 element 128) bonded to an annular base member (Figs. 3 and 7 element 124) wherein an area of the base member substantially corresponds to that of the seating portion and wherein the slit extends through the first membrane (Fig. 3), and wherein the thickness of the flow control membrane at the seating portion, as comprised of the first membrane and the annular base member, is greater than the thickness of the lumen occluding portion (Fig. 3), the flow control membrane including a seating portion at which the flow control membrane is coupled to the housing (Fig. 3 the seating portion is taken to be that generally corresponding to 119 and 124) and a lumen occluding portion having a slit (Figs. 3 and 7 see slit

Art Unit: 3767

129) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Figs. 11-13, Col. 11 lines 12-41), wherein the seating portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed (Fig. 3).

With regards to claim 3, Moorehead teaches a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 3 generally indicated at 116, Col. 10 lines 2-4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 3, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (US 5,984,902).

With regard to claims 1 and 4, Moorehead teaches a pressure activated valve (Fig. 3) for medical applications comprising: a housing having a lumen extending therethrough from a proximal end to a distal end thereof (Figs. 3 and 7 housing 112); and a flow control membrane extending across the lumen to control flow therethrough wherein the flow control membrane comprises a first membrane (Figs. 3 and 7 element 128) bonded to an annular base member (Figs. 3 and 7 element 124) wherein an area of the base member substantially corresponds to that

Art Unit: 3767

of the seating portion and wherein the slit extends through the first membrane (Fig. 3), and wherein the thickness of the flow control membrane at the seating portion, as comprised of the first membrane and the annular base member, is greater than the thickness of the lumen occluding portion (Fig. 3), the flow control membrane including a seating portion at which the flow control membrane is coupled to the housing (Fig. 3 the seating portion is taken to be that generally corresponding to 119 and 124) and a lumen occluding portion having a slit (Figs. 3 and 7 see slit 129) extending therethrough so that, when the lumen occluding portion is subjected to a pressure of at least a predetermined threshold level, the lumen occluding portion moves from a closed configuration in which flow through the lumen is prevented to an open configuration in which flow is permitted (Figs. 11-13, Col. 11 lines 12-41), wherein the seating portion covers a minority of a surface area of the lumen occluding portion in which the slit is disposed (Fig. 3). Moorehead does not explicitly disclose the first membrane and base member are adhesively bonded. However, Moorehead does teach that member 124 can be retained effectively using adhesion (Col. 10 lines 11-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to bond the first membrane and annular base member with adhesive because Moorhead teaches that adhesive is suitable for use for retention and it is an art recognized effective way of securing two things together so as to maintain them in a desired position.

With regards to claim 3, Moorehead teaches a membrane retention portion of the housing, the membrane retention portion being adapted to apply a retentive compression force to mounting portion (Fig. 3 generally indicated at 116, Col. 10 lines 2-4).

Art Unit: 3767

9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (US 5,984,902) as applied to claims 1 and 2 above, and further in view of Fischer et al. (U.S. Patent 5,944,698).

With regard to claims 5 and 6, Moorehead teaches a pressure activated valve substantially as claimed. Moorehead differs from claims 5 and 6 in that it does not disclose specific thickness range for the membrane, though it does disclose that thickness variables are determined based on the pressure that will be experienced (Col. 7 lines 30-34). However, Fischer et al. teaches a membrane with a slit that opens due to fluid pressure as a result of a plunger being inserted into a syringe barrel (Fig. 3 elements 50, 52, Col. 6 lines 6-9) and that the membrane has a preferred thickness of about .01 inches to .05 inches (Col. 6 line 5). It would have been obvious to one of ordinary skill in the art to use a first membrane with a thickness of .01- .035 inches as in claim 5 or between .01 and .05 inches as in claim 6 in the device of Moorehead as such is an art recognized membrane thickness range as exemplified in the teachings of Fischer et al. Moreover, the membrane thickness range is taken to be a result effective variable routinely optimized to correspond to the pressure the membrane will be exposed to.

With regard to claim 7, Moorehead teaches a pressure activated valve substantially as claimed. Moorehead differs from claim 7 in that it does not teach the thickness of the mounting portion to be between 1 and 20 times the thickness of the lumen occluding portion. However, Fischer et al. teaches a preferred membrane thickness of about .01 to .05 inches (Col. 6 line 5). It would have been obvious to a person of ordinary skill in the art to apply the thickness range suggested in Fischer et al. to the first membrane and base member (Figs. 3 and 7 elements 128,

Art Unit: 3767

124) in Moorehead as applied to claims 5 and 6. It directly follows that the thickness of the seating portion will be between 1 and 20 times the thickness of the lumen occluding portion.

Response to Amendment

10. The amendments to the claims have been entered and overcome the previous objection to claim 4.

Response to Arguments

11. Applicant's arguments filed February 22, 2010 have been fully considered but they are not persuasive. The rejections under 35 U.S.C. 112 regarding the recitation of the minority portion are maintained. The drawings and disclosure do not sufficiently encompass the recitation that the seating portion covers a minority of a surface area of the lumen occluding portion. Though the specification discloses the seating portion to be at the periphery there is no supporting disclosure as to the size or span of the area of the periphery. Lacking further definition the periphery of a device could encompass the majority or minority of a surface area.

Regarding Applicant's arguments with respect to Moorehead, the Examiner has identified portions 124 and 128 to constitute the flow control membrane. The seating portion is the portion of the membrane that seats against portion 115/119 generally in the area of 124. The thickness of the seating portion comprises both members 124 and 128 and is therefore thicker than the lumen occluding portion which is not covered by member 124.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772